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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/640,780	08/18/2000	Jacques Dumas	BAYER8C1	7350

23599 7590 01/03/2003

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EXAMINER

ROBINSON, BINTA M

ART UNIT	PAPER NUMBER
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1625

DATE MAILED: 01/03/2003

17

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/640,780

Applicant(s)

DUMAS ET AL.

Examiner

Binta M. Robinson

Art Unit

1625

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-79 is/are pending in the application.
- 4a) Of the above claim(s) 5-8, 10, 14, 17-42, 44 and 47-77 is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☒ Claim(s) 1-4, 9, 11-13, 15, 16, 43 and 46 is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on ____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. ____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 12.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). ____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: .

Detail d Action

The applicant traverses the restriction requirement alleging that the examiner has not presented evidence that the search and examination of groups I and II could not take place simultaneously. The applicant also alleges that no classes and subclasses for the subject matter of group II has been identified. The examiner is not required to show that the groups I and II could be searched simultaneously. The applicant is only entitled to a single, independent invention and the examiner has restricted the application to a single, independent invention. If the restriction was not applied, there would be a serious burden, because the rings which B can be such as phenyl, pyrazinyl, pyridazinyl, quinolinyl, furyl rings are classified in multiple classes of 546, 548, and 549. This is why groups I and II could not be searched simultaneously. Compounds in Group II can be classified in many classes and subclasses such as 546/329. Applicants have failed to point out the supposed errors in the restriction requirement in order to be entitled to a request for reconsideration. Applicants must point out supposed errors. Failure to do so is acquiescence. See MPEP 81803a. The restriction requirement is FINAL.

The 112, first paragraph rejection at paper no. 13 is modified.

(Modified rejection)

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is

most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1-4, 9, 11-13, 15-16, 43, 46, 78-79 are rejected under 35 U.S.C. 112, first paragraph, because the specification, does not provide enablement for A and B equal to all of the rings claimed. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims. The claims as recited are broader than the scope of enablement. The specification lacks direction or guidance for placing all of the alleged products in the possession of the public without inviting more than routine experimentation. The applicant is referred to *In re Wands*, 858 f.2d 731, 737, 8 USPQ2d 1400, 1404 (Fed. Cir. 1988) which includes the incorporation of the 8 factors recited in *Ex parte* Foreman 230 USPQ 546 (Bd. Of App. And Inter 1986).

There are many factors to be considered when determining whether there is sufficient evidence to support a determination that a disclosure does not satisfy the enablement requirement and whether any necessary experimentation is "undue". These factors include 1) the breadth of the claims, 2) the nature of the invention, 3) the state of the prior art, 4) the level of one of ordinary skill, 5) the level of predictability in the art 6) the amount of direction provided by the inventor 7) the existence of working examples, and 8) the quantity of experimentation needed to make or use the invention based on the content of the disclosure. In *re Wands*, 858 F. 2d 731, 737, 8 USPQ2d 1400, 1404 (Fed. Cir. 1988).

In terms of the first Wands factor of breadth, B encompasses a whole Markush grouping of moieties other than the substituted phenyl, pyridyl, or thiophenyl rings

claimed. The ring A encompasses many more rings than those disclosed in the specification. In terms of the fifth Wands and sixth Wands factor, the level of predictability in the art and the amount of direction provided by the inventor are low. The effect of the compounds exemplified in the specification on raf kinase activity ranges from IC_{50} s 1 to 10. The results of the cellular assay and the in vivo assay of the inhibitory effect of the compounds on tumors were not displayed for each of the specific compounds exemplified. Additionally, the applicant does not provide working examples or test data for the compounds where B can equal moieties other than substitute phenyl or pyridyl, or thiophenyl rings exemplified. The applicant also does not provide working examples where A can equal rings other than oxazolyl, isoxazolyl, pyrazolyl, thiadiazolyl, and thienyl. What cancers, cell lines, what specific tests were performed to show that cancerous cell growth has been reduced in scope? In terms of the 8th Wands factors, undue experimentation would be required to make or use the invention based on the content of the disclosure due to the breadth of the claims, the level of predictability in the art of the invention, and the poor amount of direction provided by the inventor. Taking the above factors into consideration, it is not seen where the instant claim is enabled by the instant application.

Response to Applicant's Remarks

112, first paragraph rejection

The applicant asserts that there is adequate disclosure within the specification for one skilled in the art to make the compounds recited in the claims and use them in accordance with the methods defined, without undue experimentation and that

the burden is on the examiner to show otherwise. The applicant also alleges that the 397 specific compounds identified in the tables of the specification include structures other than phenyl or pyridyl. However, the examiner notes that these compounds do not include structures in which B is other than phenyl or pyridyl. The examiner does not see where the compounds as listed in tables 1, 2.3, 3, 5.5, and 5 have B moieties equal to rings other than phenyl or pyridyl. The examiner has recited the Wands factors. The claims are so broad that more than routine experimentation is required to place the invention in the possession of the public. The applicant does not provide working examples or test data for the compounds where B can equal all of the other rings claimed. What cancers, cell lines, what specific tests were performed to show that cancerous cell growth has been reduced in scope? Without the results of cellular assays and in vivo assays for any of the claimed compounds, undue experimentation would be required to make or use the invention based on the content of the disclosure due to the breadth of the claims, the level of predictability in the art of the invention, and the poor amount of direction provided by the inventor.

The IDS at paper no. 12 has been considered.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within

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TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

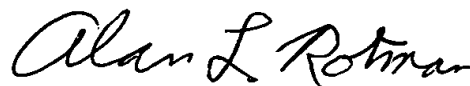
Any inquiry concerning this communication or earlier communications from the examiner should be directed to Binta M. Robinson whose telephone number is (703) 306-5437. The examiner can normally be reached on M-F (9:30-6:00).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Alan Rotman can be reached on (703)308-4698. The fax phone numbers for the organization where this application or proceeding is assigned are (703)308-7922 for regular communications and (703)308-7922 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703)308-0193.

Binta Robinson


December 30, 2002



ALAN L. ROTMAN
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1600